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**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF CALIFORNIA**
**SAN FRANCISCO DIVISION**

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA, ex rel. ZACHARY SILBERSHER,

Plaintiff,

v.

ALLERGAN PLC, ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ADAMAS PHARMA, LLC, AND ADAMAS PHARMACEUTICALS, INC.,

Defendants.

CASE NO. 3:18-cv-3018-JCS

**REPLY IN SUPPORT OF ADAMAS' MOTION TO DISMISS THE AMENDED COMPLAINT BECAUSE RELATOR IS NOT AN ORIGINAL SOURCE**

Judge: Hon. Joseph C. Spero
Date: March 17, 2023
Time: 2:00 p.m.
Place: Zoom Webinar

An original source is someone who has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government." 31 U.S.C. § 3730(e)(4)(B). Plaintiff-Relator Zachary Silbersher ("Relator") agrees that to qualify, he must provide some new information—beyond what is contained in publicly disclosed patent files—that is of value to the Government. *See* Dkt. 188 at 8-10. The essential question for this Court, thus, is whether the Amended Complaint actually provides such information. It does not.

Relator alleges that, to draft his Amended Complaint, he "retrieve[d] the prosecution histories for myriad patents using the USPTO's ungainly system, and then review[ed] those histories and the underlying documents"—in other words, Relator read publicly available records from earlier federal hearings that he downloaded from PAIR, a Government website. Dkt. 188 at 10. Recognizing this is not enough to qualify as an original source, Relator for the first time in his opposition briefing lists the "information" in the Amended Complaint that he claims is a value-add to the United States. Dkt. 188 at 8-9; Dkt. 189 at 2.[1] But none of Relator's so-called "information" sufficiently adds to the public record to make him an original source. He proffers only self-serving rhetoric and obvious background details. As discussed below, these points are not "independent" of the public patent files, nor are they "material."

*First*, Relator notes that he identified an alleged discrepancy between the 2010 Went declaration—which stated there was "no incidence" of certain side effects—and the 2012 Went declaration—which stated there was "little incidence" of those side effects. Dkt. 188 at 8; *see also* Dkt. 69-9 at 110, 138. As an initial matter, identifying this claimed discrepancy is not independent of the publicly available documents—all Relator did was read the Went declarations, which were submitted during patent prosecution and available on PAIR. Nor is identifying this discrepancy a material addition to the public record. Although Relator claims "a lay person could not have

[1] At the first motion to dismiss hearing back in 2019, Relator's counsel "concede[d]" that the public patent files disclosed "the relevant information from which the inference of fraud could be drawn." Dkt. 116 at 9:15-20. And on appeal, the Ninth Circuit noted, "it is not contested that the information underlying [Relator's] complaint was publicly disclosed." *United States ex rel. Silbersher v. Allergan, Inc.*, 46 F.4th 991, 996 n.6 (9th Cir. 2022). Only now, after four years of litigation, does Relator attempt to identify new information in his Amended Complaint. Dkt. 188 at 8-9.

alleged" what he did, Dkt. 188 at 8, no expertise is required to read two public documents and conclude that they say different things.

To the extent Relator claims his value-add lies in describing the Went declarations as "false and misleading," Dkt. 188 at 8, this is nothing more than a rhetorical spin on facts in the public record. Rhetoric and legal conclusions are not "information." Under the original source rule, "[t]he word 'information' refers to the *facts* on which the relator's allegations are based." *United States ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 239 (3d Cir. 2013) (emphasis added); *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (holding the 2010 public disclosure bar requires original sources to contribute "significant, specific details that were not publicly disclosed" and that "add[] in a significant way to the essential *factual* background: 'the who, what when, where and how of the events at issue'" (emphasis added) (citations omitted)). Relator's legal conclusions about public facts do not make him an original source. 31 U.S.C. § 3730(e)(4)(B).

*Second*, Relator claims he is an original source because he identified "[t]hat the misstatements in Defendants' patent applications were intentional." Dkt. 188 at 9. But again, Relator does nothing more than state an erroneous legal conclusion based on facts in the patent prosecution files. This conclusory statement is not independent of the publicly disclosed patent records. And it is not factual "information" at all. *See Zizic*, 728 F.3d at 239. Relator claims his Amended Complaint sheds light on Defendants' *scienter*, but in reality, his pleading simply retells the publicly available events of the patent prosecution. *See* Dkt. 188 at 9 (citing Am. Compl. ¶¶ 68-83). Relator does not offer any new facts to support his legal conclusion of fraudulent intent.

Relator claims his "years as a practicing patent attorney enabled him" to spot Defendants' allegedly nefarious intentions. Dkt. 188 at 9. This is precisely the type of claimed "expertise" that the Ninth Circuit and other courts throughout the country have deemed insufficient. *A-1 Ambulance Servs., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000) ("If a relator merely uses his or her unique experience or training to conclude that the material elements already in the public domain constitute a false claim, then a *qui tam* action cannot proceed."); *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991)

("Nonetheless, the relator must possess substantive information about the particular fraud, rather than merely background information which enables a putative relator to understand the significance of a publicly disclosed transaction or allegation."). Even Relator's cited case supports Adamas' position. *See* Dkt. 188 at 9 (citing *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 211 (1st Cir. 2016)). The *Winkelman* court expressly rejected the relator's argument that she was an original source because "her experience as a pharmacist" enabled her to provide the Government with evidence of defendant's fraudulent intent, explaining the relator provided "nothing significant" beyond what was already publicly known. *Winkelman*, 827 F.3d at 212-13.

The same is true here. Any "expertise" Relator applied is not material. Indeed, Relator does not explain why only a practicing patent attorney like him—and not the PTO Patent Examiner who reviewed each of the documents referenced in the Amended Complaint—could identify this claimed fraud.

*Third*, Relator says his Amended Complaint provides the Government with information that the at-issue patents prevented generic competition, which in turn caused the Government to pay higher prices for certain medicines. Dkt. 188 at 9. Such obvious statements about the general effect of a pharmaceutical patent are not a value-add to the Government. *Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 704 (9th Cir. 2017) (holding the allegation that the Government paid inflated prices while the defendant held its allegedly illegal pharmaceutical monopoly was "an obvious inference based on the publicly disclosed allegations"). Although Relator claims he provided "new information" to the Government via several paragraphs in the Amended Complaint, each of these paragraphs describes the public patent files without providing any novel content. Dkt. 188 at 10; *see also* Am. Compl. ¶¶ 58-61, 74-76, 80-81, 103. Relator's rhetorical flourishes—such as claiming patents were "tainted" by alleged misstatements during prosecution—do not provide materially new information as the statute requires. *See Moore*, 812 F.3d 294, 307 (3d Cir. 2016) (holding that, to be material, relator's information must "add[] in a significant way to the essential factual background").[2]

[2] Relator also purports to identify new information he provided to the Government concerning the '009 Patent. Dkt. 188 at 9. As the Amended Complaint makes clear, the Adamas Defendants did

* * *

Because the Amended Complaint lacks information that is "independent" and "materially new," Relator spends much of his briefing arguing that he need not provide anything of the sort, despite the plain text of the statute. *See* 31 U.S.C. § 3730(e)(4)(B). This is a smokescreen to obscure the true issues.

For example, despite the weight of case law cited in both motions to dismiss, Relator claims "the precedents on this matter are mixed." Dkt. 189 at 10. But Relator does not cite a single case in which a court held the relator's mere expertise made him an original source under the False Claims Act. Relator instead cites dicta from the Seventh Circuit and the Southern District of Florida. Dkt. 189 at 9-10 (citing *United States v. Bank of Farmington*, 166 F.3d 853, 864 (7th Cir. 1999) and *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, 2012 WL 2871264, at *3 (S.D. Fla. July 12, 2012)). In both cases, courts held the relators were *not* original sources, and the Eleventh Circuit ultimately rejected the dicta from *Osheroff* in a subsequent case involving the same relator. *See United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 815 (11th Cir. 2015) (holding the court was "not persuaded" by relator's argument that "he is an original source because he conducted his own investigation of the programs offered at the [at-issue medical] clinics"). Relator's only other cited case is an unpublished, Illinois state trial court decision interpreting the Illinois False Claims Act. *See* Dkt. 189 at 9. This interpretation of a different law is not persuasive and does not create a split of authority on the key issue here.

Relator also emphasizes purported legislative history, citing statements from Senator Grassley in 1999. These statements—made more than a decade before Congress passed the 2010 amendments by a legislator who voted *against* the 2010 law—are not probative of the 2010 Congress's intent.[3] And, of course, a statement from a single Senator cannot trump the statute's

not own this patent and were not involved in prosecuting it. Am. Compl. ¶¶ 91-92, 96-98, 100. Accordingly, any alleged fraud concerning the '009 Patent does not add to the publicly disclosed allegations and transactions involving Adamas. Regardless, Relator's claims concerning the '009 Patent suffer from the same deficiencies as the rest of his original source argument.

[3] Statement By Senator Grassley Regarding His Vote Against The Patient Protection And Affordable Care Act (Dec. 23, 2009), *available at* https://www.grassley.senate.gov/news/news-releases/statement-senator-grassley-regarding-his-vote-against-patient-protection-and.

plain language. *See Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 457 (2002) ("We see no reason to give greater weight to the views of two Senators than the collective votes of both Houses, which are memorialized in the unambiguous statutory text."); *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2364 (2019) ("Even those of us who sometimes consult legislative history will never allow it to be used to muddy the meaning of clear statutory language.").

Relying on his flawed conception of legislative history, Relator urges the Court to read the original source definition broadly to achieve the policy goals of deterring pharmaceutical patent fraud and "reining in high drug prices." Dkt. 189 at 6. But there is precious little support for Relator's say-so regarding Congressional intent. *See Ming Wei Chen v. Sessions*, 864 F.3d 536, 540 (7th Cir. 2017) ("Stray comments reported in the Congressional Record are [] poor indicators of a law's meaning."). And this Court's task is to apply the plain text of the statute, not shape public policy. *Silbersher*, 46 F.4th at 996 ("The language of the statute is always where we begin; if the statute is clear, we go no further.").

Relator is not, as he claims, "a paradigmatic original source." Dkt. 189 at 5. He is not a whistleblower. Try as he might, Relator cannot identify a single piece of material information in his Amended Complaint that is independent from the public patent files, nor can he identify a single case in which a relator's expertise qualified him as an original source under the Federal False Claims Act. To be an original source, Relator must provide the Government with factual information that is new and valuable. Relator's rhetorical framing of the publicly disclosed patent prosecution files does not rise to this standard. *See A-1 Ambulance*, 202 F.3d at 1245. His Amended Complaint should be dismissed with prejudice.[4]

[4] In his concluding sentence, Relator requests, without elaboration, that he be allowed to amend his pleading "should there be any deficiency." Dkt. 189 at 11. But any amendment here would be futile, so the Court should not grant leave to amend. *See Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (holding amendment is inappropriate when the plaintiff cannot cure the complaint's defects by alleging additional facts).

Dated: February 17, 2023

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